Atty Docket No.: JCLA14660 Serial No.: 10/511,018

# In the Drawings:

Please replace Figures 1-10 with the replacement drawings.

#### **REMARKS**

#### **Present Status of Application**

This is a full and timely response to the outstanding non-final Office Action mailed on November 30, 2006. The Office Action has rejected claims 2-9 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action has again objected to the drawings because the images are unclear. The Office Action has further rejected claim 1 as being anticipated by Tze et al. (WO 02/067960). Finally, the Office Action has rejected claims 1-8 under 35 USC§103(a) as being unpatentable over Tze et al. (WO 02/067960) in view of a web site article <a href="http://web.archive.org/web/\*/http://holistic-online.com/Herbal-med/Herbs/h356.htm">http://web.archive.org/web/\*/http://holistic-online.com/Herbal-med/Herbs/h356.htm</a>, Whittle (US 5,466,452), Huang et al. (US Publication 2003/0165533 A1), Yoshioka et al. (US 6,337,089), Noevir (JP Publication 2003/292432A), Nakayama et al. (US Publication 2003/0198610 A1), Ishikawa et al. (US Publication 2002/01876166 A1), Grollier et al. (US 4,767,618) and Liang et al. (US Publication 2002/0031559 A1).

Applicants have cancelled claims 1-8. After entry of the foregoing amendments, claims 9-12 remain pending in the present application. It is believed that no new matter is added by way of these amendments made to the claims or otherwise to the application.

Applicant has most respectfully considered the remarks set forth in this Office Action.

Regarding the anticipation and obvious rejections, it is however strongly believed that the cited

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references are deficient to adequately teach the claimed features as recited in the presently pending claims. The reasons that motivate the above position of the Applicant are discussed in detail hereafter, upon which reconsideration of the claims is most earnestly solicited.

## **Discussions for Drawing Objections**

The drawings are objected to because the images are still unclear due to the fact that the photographs are dark and appear to have large, black dots scattered rows all over the photographs, therefore, it is difficult to see what Applicant is trying to illustrate via the photographs.

Applicants respectfully submit to the Office that the hard copies of replacement drawings presented along with the previous response are clear, sufficiently bright, and without large, black dots scattered all over the photographs. However, applicants have noticed that the scanned copies of the drawings posted on the PAIR system are unclear as indicated by the Examiner. Applicants believe the offending areas of the drawings are resulted from the scanning of the original replacement drawings. Nevertheless, Applicants are re-submitting the original color drawings. Reconsideration and withdrawal of the objections are respectfully requested.

# Discussions for 35 U.S.C. §112, 2<sup>nd</sup> paragraph rejections

Claims 2-9 are rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 does not depend on claim 2, and Claims 1-8 have been cancelled to render the rejection moot. Withdrawal of the rejection is thereby respectfully requested.

## Discussions for 35 U.S.C. §102 & 103 rejections

Claim 1 is rejected under 35 USC §102(b) as being anticipated by Tze et al. (WO 02/067960, Tze hereinafter).

Claim 1 has been cancelled to render the rejection moot. Withdrawal of the rejection is thereby respectfully requested.

Claims 1-12 are rejected under 35 USC §103(a) as being unpatentable over Tze et al. (WO 02/067960) in view of a web site article <a href="http://web.archive.org/web/\*/http://holistic-online.com/Herbal-med/Herbs/h356.htm">http://web.archive.org/web/\*/http://holistic-online.com/Herbal-med/Herbs/h356.htm</a>, Whittle (US 5,466,452, Whittle hereinafter), Huang et al. (US Publication 2003/0165533 A1, Huang hereinafter), Yoshioka et al. (US 6,337,089, Yoshioka hereinafter), Noevir (JP Publication 2003/292432A, Noveir, hereinafter), Nakayama et al. (US Publication 2003/0198610 A1, Nakayama hereinafter), Ishiakawa et al. (US Publication 2002/01876166 A1, Ishiakawa hereinafter), Grollier et al. (US 4,767,618, Grollier hereinafter) and Liang et al. (US Publication 2002/0031559 A1, Liang hereinafter).

With regard to the 103 rejection of claims 9-12, Applicants respectfully submit that these claims defined over the prior art references for at least the reasons these prior art references, neither alone nor in combination teaches or discloses each and every element of the claim in issue.

The present invention is directed to a composition for treating dermatitis. More

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specifically, claims 9-12 of the invention teaches the specific and well-balanced concentration of each claimed component for providing the highest therapeutic effects against atopic dermatitis owing to the antibacterial, antiviral, antiallergic, antiphlogistic, blood-circulation accelerating and anti-itching effects of the claimed components.

On the other hand, Tze teaches a composition comprising herbs such as *Isatis tinctoria* and Sophora flavenscens in the form of a paste for a treatment of cancers. Yoshkoka is directed to a fabrication of a microcapsule. Although the microcapsule may be used for the delivery of the various ingredients, including Japanese angelica root extract, lemon extract.., etc., the main purpose of Yoshkoka is for the fabrication of microcapsule. Nakayama is directed to a composition for skin whitening effects and blackening prevention effects. Liang is directed to a suppository for treatment of human for infections in the upper respiratory tract. Noveir is directed to a composition for foundation and skin cleansing. According to the MPEP Chapter 2143.01, the sources for a motivation to combine references include the nature of the problem to be solved and the teachings of the prior art. The problems to be solved by these references and the teachings of these references are different from each other and from those of the present invention. Therefore, contrary to the Office's contention, the motivation to combine or to modify these references to obtain the claimed invention is lacking. Further, as acknowledged by the Office on page 11 of the office action that "... it is well known that its prima facie obvious to combine two or more ingredients, each of which is taught by the prior art, to be useful for the same purpose in order to form a third composition which is useful for the same purpose.". Since the purposes of the ingredients served in these prior art references are different those of the claimed invention, the

Office has failed to establish a prima facie obvious by combining these references.

Further, Claims 9-12 teaches the concentration <u>in volume ratios</u> of each of the claimed components. However, the prior art references, even in combination, fail to teach or suggest <u>each</u> <u>component</u> and the <u>exact concentration of each of the components</u>. The prior art references teach their ingredients in weight percents and not in volume ratios (volume percent).

Tze may teach the concentration of Herb A (including *Isatis tinctoria*) in a composition for cancer treatment is at least <u>above 5%</u> (see pg 10-12, the lowest disclosed concentration of Herb A). The present invention, however, teaches that the concentration of *Isatis tinctoria* is <u>below 1.1 wt%</u> in volume ratio. Tze may teach the concentration of Herb E (including Sophora flavescentis Ait.) in a composition for cancer treatment is at least above 2.5% (see pg. 10-12, the lowest disclosed concentration of Herb E). The present invention teaches that the concentration of Lightyellow Sophora Root is between 2.7 to 3.3% in volume ratio.

Whittle may teach the application of *Paeonia rubra* (Mouton bark) in a concentration of 25% in weight percent, *Glycyrrhiza uralenis* (licorice) in a concentration of about 32% in weight percent and *Sophora flavescens* in a concentration of about 3.8% in weight percent (see col. 5-6, Examples 3 and 4). The present invention, however, teaches that the concentration of *Paeibua suffruticosa Andr*. (Mouton bark) is about 2% and below in volume ratio, the concentration of *Glycyrrhiza uralensis Fishch*. (licorice) is below 0.55% in volume ratio, while the concentration of *Sophora flavescens* (Lightyellow Sophora Root) is about 2.7 to 3.3% in volume ratio. Whittle may have disclosed the application of white soft paraffin and Bailkal Skullcap; Whittle, however, fails

suffruticosa Andr. as taught in the instant case. As known in the art of herbal medicine, even plants from the same class and family but are of different species will have morphological and genetic differences, and thus have different properties and provide different therapeutic effects. Accordingly, neither Whittle nor other references teach <u>Paeibua suffruticosa Andr.</u> of the instant invention (Mouton Bark). Enclosed please find a copy of a document in Japanese and a partial translation of the document summarizing the different properties of Paenoia lactiflora Pall (a white kind of Paeonia while Paeonia rubra is a red kind of Paeonia) and Paeibua suffruticosa Andr..

Huang teaches the application of *Radix Angelicae Sinensis* (Jananese Angelica Root) and *Isatis indigotica Fort*. Huang, however, fails to specify the concentration of these components. Further, Huang teaches *Isatis indigotica Fort*, rather than *Isatis tinctoria L*. as taught in the present invention. As known in the art of herbal medicine, even plants from the same class and family but are of different species will have different properties and provide different therapeutic effects. Accordingly, Huang fails to teach *Isatis tinctoria L*. of the instant invention.

Yoshioka teaches a microcapsule that contains a core material of extracted components including glycyrrhiza extract, Japanese angelica root extract and lemon extract. Yoshioka merely discloses in general that the concentration of the core material may range from 0.01 to 99% by weight. Yoshioka definitely fails to teach or suggest the synergistic effects of combining the specific ingredients in good balance to obtain the optimal pharmacological effects in treating atopic dermatitis as detailed in the invention.

Noevir teaches the application of curcuma domestica Valet. (tumeric), Magnolia officinalis Rehd. Et. Wils. (magnolia bark), cnidium officinale Makino (cnidium rhizome) and Angelica acutiloba (Sieb. et Zucc. (Kitagawa)) (Angelica Radix). Noevir, however, fails to specify the concentration of these components. Further, the present invention instead teaches Curcuma aromatica Salisb (tumeric), Magnolia officinalis Rehd. Et. Wils. (magnolia bark), Ligusticum chuanxiong Hort (cnidium rhizome) and Angelica dahurica Benth Et. Hook. (Angelicae Dahuricae Root) in various concentrations in volume ratios. Since Noevir teaches different species of tumeric, magnolia bark, cnidium rhizome and Angelicae Dahuricae Root from the instant invention, Noevir fails to render the claimed invention unpatentable in this regards. Enclosed please find a declaration under Rule §1.132 signed by one of the inventor and a copy of a reference titled "Clinical Applications of Chinese Medicine", published by Ishiyaku Publishers, Inc. and a partial translation of the reference summarizing the different properties of Curcuma aromatica Salisb (Tumeric) and Curcuma domestica Valet (Wild tumeric). The reference and the translation thereof are submitted as Exhibit A of the declaration.

Nakayama teaches the application of Japanese angelica root of 0.001-20 wt%, salicylic acid in 0.0001-5 wt%, glycyrrhiza of 0.0001 to 5wt%, resorcinol of 0.0001-20wt% and angelica dahurica root in 0.001-5 wt%. On the other hand, the present invention teaches Japanese angelica root of about 0 to 0.55% in volume ratio, salicylic acid of about 0.45 to 0.55% in volume ratio, licorice of about 0 to 0.55% in volume ratio, resorcinol of about 0.45 to 0.55% in volume ratio, and angelicae Dahuricae root of about 0.9 to 1.1% in volume ratio.

**Ishikawa** teaches a moisturizer containing Amur cork tree, Cnidii rhizome, licorice, lemon in a proportion of 0.00001 to 20wt % in terms of dry solids. The present invention teaches these ingredients in volume ratios.

Grollier teaches the application of polygonum hydropiper in a concentration of 5 to 30 wt%, while the present invention teaches the polygonum cuspidatum Sieb. et Zucc (smartweed) concentration of less than 1.1% in volume ratio. Grollier may have disclosed the application of sheep oil, which the Office has alleged to be comparable to mutton oil. Grollier, however, still fails to teach the concentration of sheep oil. Further, the present invention teaches polygonum cuspidatum Sieb. et Zucc, rather than polygonum hydropiper.

Liang teaches a suppository containing *Dryobalanops Aromatica* and *Angelica Dahurica* of about 1 to 2% of the total weight for relieving infections in the upper respiratory tract. The present invention teaches Borneo Camphor tree of about 0.9 to 1.1% in volume ratio and Angelica Dahuricae root of about 0.9 to 1.1% in volume ratio.

Accordingly, even if these references were combined, the combination still fails to teach the concentration of each and every components of the claimed invention, especially for Isatis Leaf, mouton bark, Baikal skullcap, smartweed, mutton oil, alcohol, white soft paraffin and dimethylsulfoxide taught in claims 9-12. Further, since these references teach the different species of turmeric, magnolia bark, mouton bark, smartweed, the combination of these references at least fails to teach turmeric, magnolia bark, mouton bark, smartweek and the concentrations thereof as claimed in claims 9-12.

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Further, the Office relies on a total of 7 references to render claims 9-12 unpatentable. The

fact that a multiplicity of references (over three) is required to meet an invention is evidence of

unobviousness, let alone the fact that the combination of all the cited references fails to teach or

suggest each and every feature in the claims.

For at least these reasons, Applicant respectfully asserts that the prior art references fail to

render claims 9-12 unpatentable. Applicants respectfully assert that these claims also are in

condition for allowance. Thus, reconsideration and withdrawal of this rejection are respectively

requested.

**CONCLUSION** 

In view of the foregoing, it is believed that all pending claims are in proper condition for

allowance. If the Examiner believes that a telephone conference would expedite the examination

of the above-identified patent application, the Examiner is invited to call the undersigned.

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Respectfully submitted,

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